National Cancer Institute Institutional Review Board AGENDA* (revised 11/15/13)

November 18, 2013

1:00 - 5:00 pm CRC/3-1608

- 1. Review of Draft Minutes, November 4, 2013
- 2. Announcements
- 3. Old Business
- 4. New Business
- 5. NIH Problem Reports
- 6. Other Expedited Actions
 - Emergency INDs
- 7. Continuing Reviews
- **8. Response to Stips** P131324, "A Phase 2 Study of the MET Kinase Inhibitor INC280 in Papillary Renal

Cell Cancer" - Ramaprasad Srinivasan, PI

9. Amendment 10D0180-E, "A Pilot Trial Targeting mTOR as a Novel Mechanism-Based

Neoadjuvant Therapy for Head and Neck Cancer" - J Silvio Gutkind, Ph.D., PI

10. Amendment 11C0160-F, "A Pilot/Phase 2 Study of Pentostatin plus Cyclophosphamide Immune

Depletion to Decrease Immunogenicity of SS1P in Patients with Mesothelioma" -

Raffit Hassan, PI

11. Initial Review P131461, "Sonalleve MR-HIFU for Palliation of Bone Pain: Pilot Study" - Aradhana

Venkatesan, PI

12. * Initial Review P131493, "Defibrotide for Patients with Hepatic Veno-Occlusive Disease (VOD): A

Treatment IND Study"—Nirali Shah, PI